

Sent By: Onyx Pharmaceuticals;

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Remarks

Applicants will address the Examiner's remarks in the order presented by the Examiner in the Office Action mailed January 9, 2004.

Applicants acknowledge Examiners allowance of Claims 1, 2, 3, 4, 5, 6, 12, 13, and 14

Claim Objections

The Examiner has requested that claims 10 and 15 be placed in proper format. Applicants have changed the status of Claim 10 and Claim 15 in accordance with 37 CFR §1.121. Claim 10 now reads "previously amended" and Claim 15 reads "canceled".

Claim Rejections-35 U.S.C. § 112, Second Paragraph

Claims 7 – 11 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner has stated that claims 7-11 recite "said adenoviral vectors," for which there is no antecedent basis. The Examiner has suggested amending the claims to read "said adenoviral vector," and Applicants have done so.

In light of the amendments discussed above, wherein the word "vectors" has been replaced with "vector," Applicants respectfully request that the rejection be withdrawn and that these claims be allowed.

If the Examiner believes that an interview would expedite the prosecution of Applicants' patent application, the Examiner is encouraged to call the undersigned. Applicants also

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which to provide the examiner with a clean version (**Appendix A**) of the claims after the entry of this Amendment.

Applicants believe that no fees are due at this time. However, should the Commissioner determine otherwise, the Commissioner is authorized to charge any fees associated with this communication to Deposit Account No. 15-0615 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: February 23, 2004

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Appendix A
Amended Claims after Amendment

Claim 1 (previously amended): A recombinant adenoviral vector comprising a deletion in the E1b region, said deletion comprising at least a portion of the E1b 55K region gene and an E1b region gene selected from the group consisting of p19 or pIX, but retaining the E1b promoter, and substituting for said deletion a heterologous gene such that the heterologous gene has a similar temporal expression pattern as the deleted E1b region gene, and said heterologous gene having the further property of encoding a protein that has anti-tumor activity and that is operably linked to said E1b promoter.

Claim 2 (previously amended): The adenoviral vector as described in claim 1 wherein said deletion of said E1b region gene consists of said p19 gene.

Claim 3 (previously amended): The adenoviral vector as described in claim 1 wherein said deletion of said E1b region gene consists of the p19 and pIX genes.

Claim 4 (previously amended): The adenoviral vector as described in claim 1 wherein said deletion in the E1b region further comprises E1b 55K, p19, and pIX genes.

Claim 5 (previously amended): A recombinant adenoviral vector selected from the group consisting of ΔK_m TNF, $\Delta E1B/CD$ and $\Delta 55K/CD$.

Claim 6 (previously amended): The recombinant adenoviral vector as described in claim 1 wherein said heterologous gene encodes a protein selected from the group consisting of tumor necrosis factor alpha, interferon gamma, an interleukin, a cell suicide protein, cytosine deaminase, thymidine kinase and mip-3.

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Claim 7 (currently amended): Cells comprising said adenoviral vector of claim 1.

Claim 8 (currently amended): Cells comprising said adenoviral vector of claim 5.

Claim 9 (currently amended): Cells comprising said adenoviral vector of claim 6.

Claim 10 (currently amended): A method for directly treating a mammal's neoplastic condition in a mammal in need of said treatment, comprising administering to said mammal a therapeutically effective dose of said adenoviral vector of claims 1, 5, or 6.

Claim 11 (currently amended): The method as described in claim 10 further comprising administering with said adenoviral vector a chemotherapeutic or an immunosuppressive agent.

Claim 12 (previously amended): A replication competent, recombinant adenovirus selected from the group consisting of Δ KmTNF, Δ E1B/CD and Δ 55K/CD.

Claim 13 (previously presented): A recombinant plasmid selected from the group consisting of p Δ KmTNF, p Δ E1B/CD, and p Δ 55K/CD.

Claim 14 (previously presented): A recombinant plasmid selected from the group consisting of p Δ E1B, p Δ E1B/55K, and p Δ E1B/pIX.

Claim 15. Canceled